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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,589	<b>Applicant(s)</b> CARTER ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-32, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-32, 36, and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This action is in response to applicant's amendment received on 19 February 2008.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 24-32, 36, and 37 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-27, 29, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Hilaire et al. (2005/0085845 A1). Hilaire discloses a method of placing first and second stents into a bifurcation using a stent delivery device (see entire document) comprising the step of providing a first introducer (102) having a first distal portion (130) with a first distal outer diameter and a first stent (170), and a first proximal portion (110) having a first proximal outer diameter that is less than the first distal outer diameter (for example, see Figure 5). Hilaire also discloses providing a second introducer (104) having a second distal portion (132) with a second distal outer diameter and a second stent (178), and a second proximal portion (112) having a second

proximal outer diameter that is less than the second distal diameter (for example, see Figure 5).

Hilaire further discloses the steps of placing the first and second introducers in a staggered adjacent configuration, wherein the first proximal portion is adjacent to the second distal portion such that an overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter (for example, see Figure 5), placing a first (140) and second (142) wire guide in an adjacent configuration into a main lumen and first and second branch lumens, advancing the first and second introducers over the first and second wire guides positioning the first and second introducers within the main lumen and the first and second branch lumens, and deploying the first and second stents (for example, see Figure 12). With further respect to claims 24 and 37, the wire guides disclosed lead and guide the introducers, therefore, it is inherent the wire guides enter the lumens before the introducers. With further respect to claim 26, Figures 10-12 show the second wire guide tip is external to the first stent, therefore, Hilaire discloses the second wire guide is advanced external to the first stent as claimed.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hilaire et al. Hilaire teaches the method described above may be modified such that the first and second stents are deployed simultaneously (for example, see paragraph 94). It would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the stents simultaneously. Doing so would reduce the number of steps to complete the procedure, thus facilitating the procedure.

6. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hilaire et al. in view of Colgan et al. (Publication No. 2003/0040789 A1). Hilaire discloses a method as described above, however, fails to disclose the step of providing an endoscope having a working channel. Colgan discloses a method of deploying a stent (see entire document). Colgan teaches the step of providing an endoscope (70) with a working channel (72). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an endoscope with a working channel in Hilaire's method as taught by Colgan in order to be able to locate stent placement through direct vision (paragraph 87).

7. Claims 24-32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (5,669,924). Shaknovich discloses a method of placing first and second stents into a bifurcation using a stent delivery device (see entire document) comprising the step of providing a first introducer having a first distal portion (1a) with a first distal outer diameter and a first stent (6a), and a first proximal portion (shaft portion) having a first proximal outer diameter that is less than the first distal outer diameter (for example, see Figure 9). Shaknovich also discloses providing a second introducer having a second distal portion (1b) with a second distal outer diameter and a second stent (6b), and a second proximal portion (shaft portion) having a second proximal outer diameter that is less than the second distal diameter (for example, see Figure 9). Shaknovich further discloses the steps of placing a first (5a) and second (5b) wire guide in an adjacent configuration into a main lumen and first and second branch lumens, advancing the first and second introducers over the first and second wire guides positioning the first and second introducers within the main lumen and the first and second branch lumens, and simultaneously deploying the first and second stents in a side-by-side configuration (for example, see Figure 9 and column 8, lines 17-23).

Shaknovich fails to disclose the step of placing the first and second introducers in a staggered adjacent configuration, wherein the first proximal portion is adjacent to the second distal portion such that an overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter. However, the applicant discloses in the specification that the introducers may be positioned side-by-side or in a staggered configuration (for example, see paragraph 50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the introducers in a staggered configuration, since the applicant has not disclosed that a staggered configuration provides an advantage, is used for a particular purpose, or solves a stated problem over a side-by-side configuration and it appears the prior art side-by-side configuration would perform equally well as the staggered configuration. Furthermore, a staggered configuration is well known in the art (for example, see Vardi's publication 2001/0003161 A1).

8. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich in view of Colgan et al. Shaknovich discloses a method as described above, however, fails to disclose the step of providing an endoscope having a working channel. Colgan discloses a method of deploying a stent (see entire document). Colgan teaches the step of providing an endoscope (70) with a working channel (72). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an endoscope with a working channel in the Shaknovich's method as taught by Colgan in order to be able to locate stent placement through direct vision (paragraph 87).

9. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilaire et al. in view of Shaknovich. Hilaire discloses all the steps as claimed (see rejections above for a description of similar limitations) except for the step of simultaneously deploying the first and second stents within the bifurcation in a side-by-side configuration with at least a portion of the proximal portion of the second stent within the main lumen. Shaknovich discloses a method of stenting a bifurcation.

Shaknovich teaches simultaneously deploying the first and second stents within the bifurcation in a side-by-side configuration with at least a portion of the proximal portion of the second stent within the main lumen. Shaknovich teaches this configuration offers the best prospects for lack of distortion of the optimal geometry of both stents, and it permits subsequent catheter access to, and intravascular ultrasound assessment of, both distal limbs of the bifurcation (for example, see column 6, lines 31-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the steps taught by Shaknovich in Hilaire's method.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
May 7, 2008

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773